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## 105 CMR 500.000: GOOD MANUFACTURING PRACTICES FOR FOOD

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### 500.001: Purpose

The purpose of 105 CMR 500.000 is to establish minimum standards for those persons engaged in the business of processing or distributing food for sale at wholesale, including every person who prepares, manufactures, packs, repacks, cans, bottles, keeps, exposes, stores, handles or distributes food or who operates a food warehouse; maintaining a cold storage or refrigerating warehouse; manufacturing of thermally processed low-acid foods packaged in hermetically sealed containers; manufacturing of acidified foods; or transporting bakery products into the commonwealth for the purpose of sale.

### 500.002: Authority

105 CMR 500.000 is promulgated pursuant to M.G.L. c. 94 §§ 9F, 66, 67, 305A, 305C, and 305E.

### 500.003: Definitions

For the purposes of 105 CMR 500.000, the following terms shall have the meanings hereinafter specified. These definitions shall be in addition to those contained within the Federal regulations 21 CFR Part 108.00, 21 CFR Part 110.00, 21 CFR Part 113.00 and 21 CFR Part 114.00.

Adequate or approved water source and potable water are used interchangeably to mean the source of water used in the food processing operation, anywhere in the facility, shall be from an approved source meeting the quality standards of 310 CMR 22.00: Drinking Water, promulgated by the Department of Environmental Protection (DEP), or of a quality certified by a laboratory approved by DEP to meet the standards set by DEP.

Administrative Penalty means a civil administrative penalty, not to exceed five hundred dollars for any single violation, that the Department seeks to assess pursuant to M.G.L. c. 94, § 305C and 105 CMR 500.000.

Adulterated food means the definition in M.G.L. c. 94, § 186.

Air Temperature means that steady temperature determined by allowing the probe of an accurate thermometer or other appropriate means of temperature measurement to equilibrate to the temperature of a representative area of the air environment in question.

Commissioner means the Commissioner of the Department of Public Health, except where referenced in 21 CFR 108.00, 110.00, 113.00, or 114.00 relating to the Commissioner of the United States Food and Drug Administration.

Critical Violation means any violation of 105 CMR 500.000 by a facility or any other occurrence or condition in a facility that has the potential to pose a threat to public health and shall include, but not be limited to the following:

- (1) food from an unapproved or unknown source or food which is or may be adulterated, misbranded, contaminated or otherwise unfit for human consumption is found in a facility;
- (2) potentially hazardous food that is held longer than four hours for preparation or service at a temperature which is greater than 45 F (7.2 C) (in the case of cold food) or less than 140 F (60 C) (in the case of hot food);
- (3) insufficient facilities to maintain product temperature;
- (4) a person infected with a communicable disease that can be transmitted by food is working as a food handler in a food processing operation;
- (5) a person not practicing strict standards of cleanliness and personal hygiene which may result in the potential transmission of illness through food is employed in a food processing operation;
- (6) equipment, utensils and food contact surfaces are not cleaned and sanitized effectively and may contaminate food during preparation, storage or service;
- (7) sewage or liquid waste is not disposed of in an approved and sanitary manner, or the sewage or liquid waste contaminates or may contaminate any food, areas used to store or prepare food, or any areas frequented by customers or employees;
- (8) toilets and facilities for washing hands are not provided, properly installed or designed, accessible or convenient;
- (9) the supply of water is not from an approved source or is not under pressure and the food processing operation does not use single service articles and/or bottled water from an approved source;
- (10) a defect exists in the system supplying potable water that may result in the contamination of the water;
- (11) insects, rodents or other animals are present on the premises;
- (12) toxic items are improperly labeled, stored or used;
- (13) adulterated product; or

(14) power outage.

The failure to include other violations, occurrences, or conditions in this definition shall not be construed as a determination that such other violations, occurrences, or conditions are not, or may not be considered a critical violation.

Department means the Massachusetts Department of Public Health.

Division means the Division of Food and Drugs of the Massachusetts Department of Public Health.

Easily Cleanable means that surfaces are readily accessible and made of such materials and finish and so fabricated that residue may be effectively removed by normal cleansing methods.

Embargo means the definition in M.G.L. C. 94, § 189A.

Employee means the permit holder, individual having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or any other person working for a food processing operation.

Equipment means items used in the storage, preparation, display, and transportation of food such as stoves, ovens, hoods, slicers, grinders, mixers, scales, cutting blocks, tables, food shelving, reach in refrigerators and freezers, sinks, ice makers, dishwashers, steam tables, and similar items used in the operation of a food processing operation.

Facility or plant means the building or buildings or parts thereof, used for or in connection with the preparing, processing, manufacturing, packaging, repackaging, canning, bottling, keeping, exposing, storing, handling, distributing or holding of food.

Food means all articles whether simple, mixed or compound, used for food or drink, confectionery or condiment, by man or animal.

Food Processing Operation means any activity comprising any or all of the following: prepares, processes, manufactures, packs, repacks, cans, bottles, keeps, exposes, stores, handles, or distributes foods or operates a food warehouse. This includes residential kitchens licensed by the Department of Public Health to operate at wholesale.

Freezing means the removal of latent heat from the product, so that it enters a solid state.

Frozen means the product temperature has reached 0° F (-18° C) or lower at the thermal center, after thermal stabilization.

Frozen Foods means articles used for food or drink for man or other animals, which have been packaged and preserved by freezing.

Hermetically sealed container means a container designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing.

Imminent Danger to the Public Health means any violation of 105 CMR 500.000 by a facility or any other occurrence or condition in a facility that has the potential to pose a serious threat to public health and shall include, but not be limited to:

- (1) a loss of water supply for four hours or longer;
- (2) the use of an unapproved source of water within the facility;
- (3) a failed sewer system or a sewage backup into the facility;
- (4) a power outage lasting four hours or longer;
- (5) facility has been subject to one or more of the following; flood, fire, chemical exposure, natural disaster and/or other catastrophic event;
- (6) an employee found to be infected with a communicable disease as described in 105 CMR 500.016, or
- (7) severe unsanitary conditions that threaten to contaminate the facility, a part of the facility or a particular product;

The failure to include other violations, occurrences, or conditions in this definition shall not be construed as a determination that such other violations, occurrences, or conditions are not, or may not be considered an imminent danger to public health.

Inspector means an agent of the Commissioner of the Massachusetts Department of Public Health as defined in M.G.L. C 111, § 9.

Label or Labeling means the definition in M.G.L. c. 94, § 1 and the requirements established in 105 CMR 520.000: Labeling, as they pertain to food processing operations.

Law means any applicable federal, state and local statutes, ordinances, and regulations.

License means any license or permit required by law or by regulation or order of the Department.

Licensee means any person who holds a currently valid license or permit from the Department to operate a food processing operation.

Misbranded food means the definition in M.G.L. c. 94, § 187.

Noncompliance, Failure to Comply and Violation each mean any act or failure to act which constitutes or results in one or more of the following:

(1) engaging in any food processing operation subject to regulation by 105 CMR 500.000 or applicable statute, without a license or permit, whenever engaging in such an operation requires a license or permit.

(2) engaging in any activity prohibited by, or not in compliance with, these regulations, or any order or license issued or adopted by the Department pursuant to these regulations or applicable statute.

(3) failing to do, or failing to do in a timely manner, anything required by these regulations, or any order or license issued or adopted by the Department pursuant to these regulations or applicable statute.

Person means any individual, partnership, corporation, association, or other legal entity.

Person In Charge means the individual present in the facility who is the actual or apparent supervisor of the facility at the time of the inspection.

Potentially Hazardous Food means any food or ingredient, natural or synthetic, in a form capable of supporting

(1) the rapid and progressive growth of infectious or toxigenic microorganisms or

(2) the slower growth of *C. botulinum*. Included are any foods of animal origin, either raw or heat treated, and any foods of plant origin which have been heat treated and raw seed sprouts.

(3) excluded are the following:

(a) air dried hard boiled eggs with shells intact;

(b) foods with a water activity (aw) value of 0.85 or less;

(c) foods with a hydrogen concentration (pH) level of 4.6 or below;

(d) foods in unopened hermetically sealed containers, which have been commercially processed to achieve and maintain commercial sterility under conditions of non refrigerated storage and distribution; and,

(e) foods for which laboratory evidence (acceptable to the Department) demonstrates that rapid and progressive growth of infectious and toxigenic microorganisms or the slower growth of *C. botulinum* cannot occur.

Refrigeration means mechanical lowering of (PHF'S) foods to below 45 F

Residential Kitchen means a kitchen in a private home.

Safe material means articles manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food. If materials used are food additives or color

additives as defined in the Federal Food, Drug, and Cosmetic Act (21 USC §§ 301 et seq.), they are "safe" only if they are used in conformity with regulations established pursuant to 21 USC §§ 301 et seq. Other materials are "safe" only if, as used, they are not food additives or color additives as so defined, and are used in conformity with all applicable regulations of the Food and Drug Administration.

Safe temperatures as applied to potentially hazardous food, means temperatures of 45 F (7.2 C) or below and 140 F (60 C) or above unless otherwise specified in 105 CMR 500.000, and 0 F (18 C) or below for frozen foods.

500.004: Adoption of Federal Regulation 21 CFR Part 108.00: Emergency Permit Control

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 108.00: Emergency Permit Control published and revised from time to time by the United States Department of Health and Human Services, including all of its appendices and all other regulations, standards, memoranda or other documents it refers to and/or incorporates (to the extent they relate to emergency permit control) as well as all subsequent revisions or amendments to said regulation, appendices or referenced documents, to the extent they are not inconsistent with specific provisions of 105 CMR 500.000.

500.005: Adoption of Federal Regulation 21 CFR Part 110.00: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 110.00: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food published and revised from time to time by the United States Department of Health and Human Services, including all of its appendices and all other regulations, standards, memoranda or other documents it refers to and/or incorporates (to the extent they relate to the manufacture, packing or holding of human food) as well as all subsequent revisions or amendments to said regulation, appendices or referenced documents, to the extent they are not inconsistent with specific provisions of 105 CMR 500.000.

500.006: Adoption of Federal Regulation 21 CFR Part 113.00: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 113.00: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers published and revised from time to time by the United States Department of Health and Human Services, including all of its appendices and all other regulations, standards, memoranda or other documents it refers to and/or incorporates (to the extent they relate to thermally processed low-acid foods packaged in hermetically sealed containers) as well as all subsequent revisions or amendments to said regulation, appendices or referenced documents, to the extent they are not inconsistent with specific provisions of 105 CMR 500.000.

500.007: Adoption of Federal Regulation 21 CFR Part 114.00: Acidified Foods

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 114.00: Acidified Foods published and revised from time to time by the United States Department of Health and Human Services, including all of its appendices and all other regulations, standards, memoranda or other documents it refers to and/or incorporates (to the extent they relate to acidified foods) as well as all subsequent revisions or amendments to said regulation, appendices or referenced documents, to the extent they are not inconsistent with specific provisions of 105 CMR 500.000.

500.008: Supplemental Good Manufacturing Practices for Food Regulations

The following conditions are in addition to those established in 105 CMR 500.004, 500.005, 500.006, and 500.007:

(A) Open Dating:

All perishable or semi-perishable food products covered by 105 CMR 500.000 shall meet the open dating requirements set forth in 105 CMR 520.000 et seq.: Labeling

(B) Frozen and Refrigerated Foods:

(1) Delivery and Transportation

(a) frozen and refrigerated food delivery trucks shall be equipped with a combination of insulation and mechanical refrigeration, capable of maintaining a product temperature of 0° F (-18° C) or lower for frozen foods and 45° F (7.2° C) or lower for refrigerated foods, while loaded with any frozen or refrigerated foods.

(b) frozen and refrigerated food delivery trucks shall be equipped with a thermometer or other appropriate means of temperature measurement, indicating air temperature inside the vehicle. The dial or reading element of the thermometer shall be mounted on the outside of the vehicle in a readily accessible position, in order that the trucker may determine whether or not the refrigeration unit is operating properly.

(c) the internal product temperature for any individual consignment of frozen foods shall not exceed 0° F (-18° C) or for refrigerated foods shall not exceed 45° F (7.2° C) during any loading, transportation or unloading of said consignment.

(d) frozen or refrigerated foods shall be loaded and unloaded as fast as possible to insure a minimum of exposure to temperatures above 0° F (-18° C) or 45° F (7.2° C), whichever is appropriate.

(e) frozen and refrigerated foods shall be transported under sanitary conditions in accordance with good commercial practice.

(2) Handling Practices for Over-the-Road Transportation.

(a) vehicles shall be pre-cooled before loading.

(b) frozen and refrigerated foods destined for direct consumer use shall be securely packaged or wrapped in a sanitary manner before they are offered for transportation. Other frozen or refrigerated foods shall be shipped in accordance with good sanitary practice.

(c) no frozen or refrigerated food shipment shall be accepted for transportation when the internal product temperature exceeds 0° F (-18° C) for frozen food or 45° F (7.2° C) for refrigerated food.

(d) frozen and refrigerated foods shall be loaded within a vehicle of transportation so as to provide for free circulation of refrigerated air to the front, rear, top, bottom and both sides of the load, except for vehicles of envelope type construction wherein refrigerated air circulates within walls of said vehicles.

(e) frozen and refrigerated foods shall be handled expeditiously during any loading or unloading of said consignment, so as not to be unreasonably exposed to temperatures above 0° F (-18° C) or 45° F (7.2° C), as appropriate.

(f) the mechanical refrigerating unit of vehicles shall be turned on, and doors of vehicles shall be kept closed during any time interval when loading or unloading operations cease or are interrupted.

(C) Residential kitchens: Wholesale Sale

(1) No person shall operate a residential kitchen at wholesale without a valid license granted by the Department or in violation of the specific requirements for residential kitchens under 105 CMR 500.000.

(2) Residential kitchens for wholesale sale shall comply with the minimum requirements of 105

CMR 500.000, except that federal regulation sections 21 CFR 110.37 (e)(4) and 110.80 (b)(3), as adopted by reference in 105 CMR 500.005, are not applicable.

(3) Food Preparation and Protection

(a) only non-potentially hazardous foods and foods that do not require refrigeration shall be prepared in or distributed from a residential kitchen for wholesale to the public. Ingredients that are potentially hazardous foods, such as milk, cream, and eggs, may be used in food preparation for the public provided that the final product is not a potentially hazardous food.

(b) low-acid foods packaged in hermetically sealed containers, modified atmosphere packaged foods, acidified foods, dairy products and meat and poultry products shall not be prepared in a residential kitchen.

(c) except when washing fruits and vegetables or when in compliance with the Department's policy on alternative procedures for bare hand contact with ready-to-eat food, residential kitchen workers may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves or dispensing equipment.

(4) Who May Work Only immediate family members residing in the household may prepare food for wholesale in a residential kitchen.

(5) General Requirements for Residential Kitchens for Wholesale Sale

(a) Storage. Separate dry and refrigeration storage facilities must be utilized for raw ingredients and finished food products.

(b) Handwashing. A soap dispenser and disposable towels for use in handwashing shall be provided at the kitchen sink. This sink shall not be used for handwashing after toilet use but may be used for food preparation and warewashing provided it is cleaned and sanitized prior to and between different uses.

(c) Toilet Room. A toilet room shall be available for use by food employees. Toilet rooms opening to the kitchen shall have adequate ventilation. Ventilation must be provided by mechanical means or by screened windows. A soap dispenser and disposable towels shall be provided for handwashing in toilet rooms used by food employees.

(d) Manual Cleaning and Sanitizing. For manual cleaning and sanitizing of cooking equipment, utensils and tableware, three compartments shall be provided and used; or a two compartment sink may be used when an approved detergent sanitizer is used in accordance with manufacturer's instructions. The strength of the sanitizer must be measured as necessary and recorded in a log. Log records shall be kept on file for 90 days.

(e) Mechanical Cleaning and Sanitizing. A domestic or home style dishwasher may be used provided the following performance criteria are met:

1. The dishwasher must effectively remove physical soil from all surfaces or dishes, equipment and utensils.

2. The operator shall provide and use daily a maximum registering thermometer or a heat thermal label to determine that the dishwasher's internal temperature is a minimum of 150° F after the final rinse and drying cycle. Records of this testing shall be kept on file for 90 days.

3. The dishwasher must be installed and operated according to manufacturer's instructions for the highest level of sanitization possible when sanitizing residential kitchen facilities' utensils and tableware; a copy of the instructions must be available on the premises at all times.

4. There shall be sufficient area or facilities such as portable dish tubs and drain boards for the proper handling of soiled utensils prior to washing and of cleaned utensils after sanitization so as not to interfere with safe food handling, handwashing and the proper use of warewashing facilities. Equipment, utensils and tableware shall be air-dried.

(6) Premises

(a) Pets may be present on the premises, but shall be kept out of food preparation areas during food preparation and out of food storage areas at all times.

(b) Laundry facilities may be present in the kitchen, but shall not be used during food preparation.

(c) Cooking facilities in the kitchen shall not be used for domestic purposes during preparation of food for wholesale.

(d) Garbage receptacles. Impervious covered receptacles shall be provided for storage of garbage and refuse.

(e) Water supply. Hot and cold water under pressure shall be provided to food preparation areas and toilets and shall be from an approved source.

(f) Sewage. Shall be disposed of through an approved system that is:

1. A public sewage treatment plant; or

2. An individual sewage disposal system that is sized, constructed, maintained, and operated according to law.

500.010: General Administration

(A) Enforcement Policy

The following provisions shall cover the administration and enforcement of 105 CMR 500.000.

(B) The purpose of the enforcement program is to promote the protection of the public health by:

(1) ensuring compliance with regulations and conditions of licensure;

(2) obtaining prompt correction of violations and adverse quality conditions which may affect public health;

(3) deterring future violations and occurrences of conditions adverse to public health; and

(4) encouraging improvement of good manufacturing practices for individual licensees, and by example, that of the industry, including prompt identification and reporting of potential health or sanitation problems.

(C) The Department may from time to time publish interpretations of 105 CMR 500.000 and guidelines as necessary to promote uniform application of 105 CMR 500.000, and may make them available to those persons licensed under 105 CMR 500.000. The Department may advise licensees or local boards of health on particular questions regarding the interpretation of 105 CMR 500.000.

(D) The Department may enforce 105 CMR 500.000 by issuing an order to correct violations or an order to cease and desist operation of a facility or a specific operation of the facility, or by commencing an enforcement action pursuant to 105 CMR 500.017.

(E) 105 CMR 500.000 shall apply to food processing operations under the jurisdiction of local boards of health, which license food service establishments pursuant to 105 CMR 590.000, to the extent that such food service operations also contain food processing operations. The local boards of health shall enforce the standards established in 105 CMR 500.000 with regard to food processing operations under their jurisdiction.

500.011: Licensure

(A) No person shall operate a food processing operation without a valid license granted by the Department or in violation of the terms of a valid license or the requirements of 105 CMR 500.000.

(B) A person who desires to operate a plant for a food processing operation(s) within Massachusetts shall submit an application for a license to the Department. Such application shall be on a form provided by the Department.



(C) Only a person who complies with the requirements of 105 CMR 500.000 shall be entitled to receive and retain a license. A license shall be valid only for the licensee indicated on the license and only for the location indicated on the license.

(D) A license shall remain in effect for the period specified by statute.

(E) A license may be renewed by applying at least thirty (30) days prior to the expiration of the license. Application for renewal shall be made in writing on a form provided by the Department.

(F) No licensee shall transfer or assign a license in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any company. No licensee shall operate pursuant to a license transferred or assigned by a prior licensee.

(G) Notification to the Department

(1) a licensee shall notify the Department immediately upon change in ownership or plant location and shall immediately relinquish to the Department its license upon transfer of ownership or change of location. A licensee shall notify the Department at least thirty (30) days prior to any change of the name of the plant. The new owner in a change of ownership or the licensee, in the case of a new location, shall submit to the Department an application for a new permit, and shall not operate until said license is issued. A change in name only shall require the licensee to submit to the Department an application for an amended license, together with written documentation reflecting the change in name.

(2) a licensee shall promptly notify the Department any time that a plant is being remodeled. Upon notification, the Department may inspect the plant to verify compliance with 105 CMR 500.000.

(3) a licensee shall notify the Department immediately when an imminent danger to the public health is present in the plant.

(H) No person shall transport or cause to transport any bakery product into the Commonwealth for the purpose of sale without obtaining a license or permit from the Department, pursuant to applicable law.

(1) after receipt of an application for a license or permit, the Department shall review the application and any documents filed with it. To determine the extent of the plant's compliance with 105 CMR 500.000 the Department may accept reports of the responsible authorities in the jurisdiction where the facility is located. When information reveals that the requirements of 105 CMR 500.000 have been met, the Department shall issue a license or permit to the applicant.

(2) each license or permit granted by the Department pursuant to this provision shall apply to one plant only, and shall be valid throughout Massachusetts.

500.012 Food Processing Operation Operating without a License

(A) The Department may inspect any facility for which it has a reasonable belief contains a food processing operation.

(B) The Department may issue a cease and desist order to any person engaged in a food processing operation without a license.

(C) The Department may deny an application for a license where the applicant was previously operating a facility without a license.

(D) The Department may impose administrative penalties for each day that a facility, subject to licensure under M.G.L. c. 94, § 305C, is operated without a license.

(E) Operation of a facility, subject to licensure pursuant to M.G.L. c.94, § 305C, without a license shall subject a person to a fine of not more than one thousand dollars. The superior court shall have jurisdiction to enjoin the operation of a facility without a license.

(F) The Department may take such other steps as required to bring a facility operating without a license into compliance or to terminate the operation of the facility, in order to protect the health and safety of the public.

#### 500.013: Inspections

(A) To carry out properly its responsibilities under 105 CMR 500.000 and applicable statutes and to protect properly the health and well-being of the people of the Commonwealth, the Department, or an authorized agent or representative of the Department, is authorized, as often as is deemed necessary for the enforcement of 105 CMR 500.000, to enter, examine, or survey any facility engaged in a food processing operation. Upon reasonable belief that a person is engaged in a food processing operation without a license, the Department is authorized to inspect the facility.

(B) Inspections may be random systematic inspections of facilities or in response to a specific complaint. An inspection initiated from a specific complaint is not limited to that complaint. At the time of the inspection, the inspector may record all violations.

(C) Agents of the Department, after identifying themselves, may enter all areas of any facility described in subparagraph (A) above, at any reasonable time, for the purpose of making an inspection to ascertain whether the facility is in compliance with 105 CMR 500.000. Any reasonable time includes unannounced inspections, which do not require prior notification of the facility. Individuals engaged in food processing operations shall provide access to Department inspectors at any reasonable time for inspection of the premises.

(D) Agents of the Department may examine all records of the facility to determine which are relevant to the enforcement of 105 CMR 500.000 and all relevant statutes, and further agents may copy all records that are relevant.

(E) The licensee, applicant, or the person in charge at the time of the inspection shall furnish the agent of the Department with all requested records and shall provide the agent with access to all areas of the facility.

(F) If the licensee, applicant, or person in charge at the time of the inspection refuses entry to an agent of the Department, refuses to permit an authorized inspection, or interferes with the Department, or any agent thereof, in the performance of its duties, the Department may:

(1) seek in a court of competent jurisdiction an administrative search warrant to search the premises. The warrant application shall apprise the applicant, licensee, or owner of the facility concerning the nature of the inspection and justification for it and the Department may seek the assistance of police authorities in presenting the warrant; and/or,

(2) take steps to refuse to issue or renew, suspend or revoke such license or to impose administrative penalties or fines in accordance with M.G.L. c. 94, §§ 9E, 10, 73, 305A, 305C or 305E.

#### 500.014 Notice of Violations/Order to Correct

(A) Whenever the Department finds upon inspection, investigation of a complaint or through information in its possession that an applicant or licensee is not in compliance with the provisions of 105 CMR 500.000, the Department shall notify the applicant or licensee of each violation or deficiency. The notice shall include a statement of the violations or deficiencies found; the provision of the law relied upon; the level of severity of the violation or deficiency, when appropriate; a reasonable period of time for correction; and notice that a violation or deficiency may result in a refusal to issue or renew or a suspension or revocation of a license, a modification or limitation of a license, a cease and desist order, and/or the imposition of administrative penalties.

(B) The reasonable period of time for correction shall be within the discretion of the Department to establish in each instance, and shall be based on an evaluation of the type and the severity of each violation or deficiency.

(C) The Department's inspection report shall constitute the Notice of Violations and the Order to Correct all violations or deficiencies so indicated.

(D) The applicant or licensee shall be responsible for the correction of all violations or deficiencies or the compliance with any order issued pursuant to 105 CMR 500.000 and applicable statutes.

(E) Service of the Notice of Violations/Order to Correct:

(1) service shall be in person to the applicant or licensee or the person in charge at the time of the inspection, or by certified mail, return receipt requested at the address indicated on the application or license, or any subsequent address provided to the Department by the applicant or licensee;

(2) if served personally, notice is deemed to be issued on the date when the report is delivered personally;

(3) if served by certified mail, return receipt requested, notice is deemed to be issued on the second business day after it is mailed.

#### 500.015 Plan of Correction

(A) The applicant or licensee, within ten (10) calendar days of issuance of the Notice of Violations/Order to Correct, shall:

(1) correct all violations or deficiencies and file a certification of correction with the Department; and/or,

(2) for those items not certified as corrected, file a written plan of correction with the Department.

(B) Each plan of correction and each certification shall:

(1) state the name of the applicant or licensee and the name of the individual and address for receipt of notices;

(2) reference each violation or deficiency cited, and for each indicate:

(a) the specific corrective action taken and the date the work was completed; and/or,

(b) where, corrective action was not yet completed, the specific corrective action planned and the time table and date for completion, which is in accordance with the date indicated in the Notice of Violations/Order to Correct; and

(3) include the date and the signature of the applicant or licensee or his official designee, sworn to under the pains and penalties of perjury.

(C) If the applicant or licensee cannot complete the corrective action within the time frame designated in the Notice of Violations/Order to Correct, the applicant or licensee must petition the Department in writing for an extension of the time to correct. Any petition to extend the time to correct must be submitted to the Department prior to the date indicated in the Notice of Violations/Order to Correct for the violation or deficiency to be corrected. An untimely petition for extension will not be considered unless good cause can be established for the failure to timely file. A petition for an extension of time shall include the reason(s) that the correction cannot be timely completed (e.g. the work requires a permit which will not be issued within the time period granted), including documentary evidence in support and a specific time by which the facility will complete corrections. The Department shall notify the applicant or licensee whether an extension of the time is granted and the duration of the extension, if it is granted.

(D) The Department may reinspect a facility to determine whether the corrections were completed.

(E) If upon review of the plan of correction and/or upon reinspection the Department finds that an applicant or licensee remains noncompliant with applicable laws and regulations, the Department may initiate enforcement procedures as set forth in 105 CMR 500.017, or it may request that the applicant or licensee amend and resubmit the plan of correction within ten (10) calendar days of the issuance of the notice or such other time as the Department may specify for resubmission.

#### 500.016: Procedures When Infection is Suspected

(A) Pursuant to M.G.L. c. 94, § 305B, when the Department or the board of health, where applicable, has reasonable cause to suspect disease transmission by an employee of a licensee it shall:

(1) secure a morbidity history of the suspected employee, and make any other investigation as warranted by the circumstances; and

(2) take any other action required by 105 CMR 300.000: Reportable Diseases and Isolation and Quarantine Requirements.

(B) The board of health, where applicable, shall immediately notify the Division of Food and Drugs of suspected disease transmission, and shall keep the Division informed until any investigation is completed.

(C) The Commissioner or his designee, on his own initiative, or at the request of a local board of health, may require any employee whose duties actually involve the handling of food products, or product contact surfaces to submit to a medical examination, which may include the taking of samples of body fluids, secretions or excretions, whenever said Commissioner or his designee has reason to believe that such examination is necessary for the protection of the public health. The examination shall be without charge to the person examined and at the expense of the Department or of the board of health requesting it.

(D) In addition, the Department or the board of health, where applicable, may require either or both of the following measures:

(1) restriction of a suspected employee's services to areas of the facility where there will be no danger of the suspected employee contaminating food products, or product contact surfaces with pathogenic organisms or transmitting disease to other persons;

(2) the immediate closing of the facility concerned until, in the opinion of the Department or the board of health, where applicable, no further danger of disease outbreak exists.

(E) The licensee, person in charge or manager of any food facility, when he or she knows, or has reason to believe, that any employee has contracted any disease transmissible through food or food products, or has become a carrier of such a disease, shall immediately notify the Division.

(F) Any employee who fails to cooperate with any medical or laboratory examination ordered by the Commissioner of Public Health or his or her designee or the local board of health, where applicable, shall immediately be excluded from the performance of duties involving the handling of food or food products, or product contact surfaces.

(G) The following diseases are known to be transmissible through food or food products

(1) Listeriosis;

(2) Yersiniosis;

(3) Campylobacteriosis;

(4) Salmonellosis;

(5) E coli 0157: H7;

- (6) Hepatitis A;
- (7) Shigella; and
- (8) Staphylococcal Intoxication

This list is not intended to be exclusive, and the Department may, in a given case, determine that a risk of transmission exists from a disease not specified above.

#### 500.017: Enforcement

##### (A) Summary Suspension without a Prior Hearing

(1) in accordance with M.G.L. c. 94, § 305C, the Commissioner may, without a prior hearing, suspend a license if he finds that the licensee is operating his business in a manner which is endangering or may cause imminent danger to the public health.

(2) a summary suspension order shall be in writing and shall be immediately provided to the licensee or to the person in charge of the facility and a copy shall be posted at the facility. The order shall state:

- (a) the reason(s) for the summary suspension;
- (b) the violation(s) leading to the determination that the business is operating in a manner which is endangering or may cause imminent danger to the public health and the applicable provision of law;
- (c) that all operations or one or more operations of the facility shall immediately cease and desist; and
- (d) that a hearing shall be afforded pursuant to the procedures established in 105 CMR 500.017(H).

(3) the order immediately suspending the license shall be effective upon posting of the order at the facility by an authorized agent of the Department. If the person whose name appears on the license is not present at the time of such posting, or if the licensee is a corporation or other firm, a copy of the order of suspension shall also be served in accordance with 105 CMR 500.017(G)

(4) the Department may end the summary suspension at any time if reasons for the suspension no longer exist.

##### (B) Refusal to Issue a License

(1) the Department may refuse to issue a license based on any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to refuse to issue a license:

- (a) failure to submit a license application in accordance with the Department's procedures;
- (b) failure to submit the required license fee;
- (c) failure to comply with any provisions of 105 CMR 500.000;
- (d) denial of entry to agents of the Department or any attempt to impede the work of a duly authorized agent or representative of the Department;
- (e) providing false or misleading statements to the Department;
- (f) the applicant operated the facility or any facility without a license or upon the expiration of a license;
- (g) the applicant or, if the applicant is a corporation, a corporate officer or the owner of the facility, has been convicted of, pled guilty or nolo contendere to, or has, in a judicial proceeding, admitted facts sufficient to find that s/he is guilty of a crime relating to the processing, storage, distribution or sale of food in connection with the business;
- (h) the applicant or, if the applicant is a corporation, a corporate officer or the owner of the facility has engaged in conduct that endangers the public health;
- (i) a facility owned or operated by the applicant which is, or was, the subject of a proceeding(s)

and which proceeding is still ongoing or resulted in the suspension, denial, or revocation of a license or refusal to renew the license;

(j) failure to pay any federal, state or local taxes as required by law; pursuant to M.G.L. c. 62C, § 49A; or

(l) failure to pay administrative penalties or fines levied in accordance with M.G.L. c. 94, §§ 9E, 10, 73, 305A, 305C, or 305E; or

(m) failure to comply with local regulations/ordinances related to the operation of the facility.

(2) Notice of Refusal to Issue a License:

(a) shall be in writing and shall specify the specific reasons(s) for which the license was denied, the applicable provision of law and the procedure for requesting a hearing set forth in 105 CMR 500.017(H), unless no hearing is required pursuant to M.G.L. c. 30A, § 13; and

(b) shall be served on the applicant in accordance with 105 CMR 500.017(G).

(3) Hearing: to obtain a hearing, the applicant shall follow the procedures set forth in 105 CMR 500.017(H).

(C) Suspension, Revocation, or Refusal to Renew a License and Imposition of Administrative Penalties after Opportunity for a Hearing

(1) Suspension: The Department may suspend a license to operate a facility or one or more particular operations of the facility if the facility or the operation does not comply with any one or more of the requirements of 105 CMR 500.000. The suspension shall continue until the Department determines that the required corrections are made.

(2) Revocation: The Department may revoke a license to operate a facility or to terminate a particular operation, if the facility or operation does not comply with any one or more of the following grounds. Each of the grounds shall constitute full and adequate grounds to revoke a license:

(a) repeated violations of any of the requirements of 105 CMR 500.000;

(b) interference with the Department or any of its authorized agents in the performance of its duties including, but not limited to, refusal to provide access to inspect any part of the premises;

(c) a criminal conviction of the licensee, or if the licensee is a corporation a criminal conviction of a corporate officer or the owner of the facility, for a crime relating to the processing, storage, distribution or sale of food in connection with the licensed business;

(d) keeping or submitting any misleading or false records or documents required by 105 CMR 500.00 or related law;

(e) failure to pay any federal, state or local taxes as required by law; pursuant to M.G.L. c. 62C, § 49A; or

(f) failure to pay administrative penalties or fines levied in accordance with 105 CMR 500.000 and M.G.L. c. 94, §§ 9E, 10, 73, 305A, 305C, or 305E.

(D) Refusal to Renew a License: The Department may refuse to renew a license if the facility does not comply with any one or more of the following grounds. Each of the grounds shall constitute full and adequate grounds to refuse to renew a license:

(1) any of the grounds specified in 105 CMR 500.017 (A);

(2) any of the grounds specified in 105 CMR 500.017 (B); or,

(3) any of the grounds specified in 105 CMR 500.017 (C).

(E) Administrative Penalties: The Department may assess administrative penalties, pursuant to M.G.L. c. 94, §305C, in lieu of, or in addition to, suspending, revoking or refusing to issue or renew a license, or other enforcement procedures.

(1) administrative penalties may be imposed against any person for one or more of the following

grounds:

(a) failure to timely correct a violation or deficiency that constitutes a critical violation. Penalties shall accrue from the date set for correction in the Notice of Violations/Order to Correct, until the violation or deficiency is corrected;

(b) the imposition or noticing of a second non-critical violation for the same deficiency within any twelve (12) month period. Penalties shall accrue from the date set for correction in the Notice of Violations/Order to Correct of the second non-critical violation or deficiency until the violation or deficiency is corrected;

(c) denial of entry to agents of the Department or any attempt to impede the work of a duly authorized agent or representative of the Department. Penalties shall accrue from the date of the denial of entry, for each day until agents of the Department are granted unimpeded access;

(d) failure to comply with a cease and desist order of the Department. Penalties shall accrue from the date of the issuance of the cease and desist order, until there is full compliance with the order;

(e) false certification of correction pursuant to 105 CMR 500.015(A); or

(f) the operation of a facility without a license. Penalties shall accrue for every day of operation without a license.

(2) Determining the Money Amount of an Administrative Penalty

(a) Maximum Penalty: Pursuant to M.G.L. c. 94, § 305C, the maximum administrative penalty for the violation of any rule or regulation is not to exceed five hundred dollars for any single violation.

(b) Level of Administrative Penalty:

1) the penalty shall be \$500.00 for each day that a person fails to comply with a critical violation.

2) the penalty shall be \$100.00 for each day that a person fails to comply with a non-critical violation.

3) the penalty for a false certification of correction shall be \$200.00 for each violation falsely certified.

4) the penalty for the denial of entry to or impeding the work of a duly authorized agent or representative of the Department shall be \$300.00 for each time entry is denied or work is impeded.

5) the penalty shall be \$500.00 for each day that a person fails to comply with a cease and desist order of the Department. and,

6) the penalty shall be \$500.00 for each day that a person operates a facility without a license.

(c) Repeated Noncompliance: Each day during which each noncompliance occurs or continues shall constitute a separate violation/offense and shall be

subject to a separate penalty, not to exceed five hundred dollars per day, per violation. If noncompliance continues for any part of a day, that day shall be included in the calculation.

(d) Calculating the Duration of Continued and/or Repeated Noncompliance: Noncompliance shall be calculated commencing from the date set for compliance above. Penalties shall be assessed for each day of noncompliance, commencing on the date set above in 500.017(E)(1) until the day when the person comes into compliance or the day when the adjudicatory proceeding on the penalty assessment is ended. However, nothing in this section relieves the person from accruing further penalties on the same violations commencing on the day following the conclusion of the adjudicatory hearing, which would form the basis of a future enforcement action.

(e) Waiver of the Right to an Adjudicatory Hearing: If the right to a hearing is affirmatively

waived within ten (10) days, as provided for in 105 CMR 500.017 (H), the Department shall reduce the administrative penalty amount by thirty-five (35) percent. If the person does not waive its right to a hearing in writing in accordance with the procedures outlined herein, the administrative penalty shall not be reduced by thirty-five (35) percent.

(f) Paying an Administrative Penalty: If after a hearing, or waiver thereof, the Department imposes an administrative penalty, the administrative penalty shall be due and payable by certified check, cashier's check, or money order payable to the order of the Commonwealth of Massachusetts on or before the thirtieth (30) day after the final agency action. No other form of payment shall be accepted.

(F) Notice of Intent to Suspend, Revoke or Refuse to Renew a License or to Impose Administrative Penalties:

(1) shall be in writing and shall specify the specific violation(s) including the condition constituting the violation and the applicable provision of law for which the license is to be suspended, revoked or not renewed or for which administrative penalties are to be imposed and the procedure for requesting a hearing set forth in 105 CMR 500.017(H).

(2) in the case of a notice of intent to impose administrative penalties, it shall also include the money amount, to date, which is to be assessed as a penalty for each alleged act or omission; and,

(3) shall be served on the licensee or other responsible person in accordance with 105 CMR 500.017(G).

(G) Service of Orders and Notices of Intent

(1) Each applicant and licensee shall provide the Department with its complete and correct mailing address. Each applicant and licensee shall notify the Department within seven (7) calendar days of the change of its mailing address. The address provided to the Department shall be deemed the appropriate address for the service of all orders and notices from the Department.

(2) orders for immediate suspension or refusals to issue a license and notices of intent to suspend, revoke, refuse to renew a license, or impose administrative penalties shall be served by an agent of the Department on the applicant or licensee or his authorized agent as follows:

(a) by certified mail, return receipt requested at the address provided pursuant to subsection (1) above; or

(b) in hand service.

(H) Hearings:

(1) the Department shall conduct all adjudicatory proceedings in accordance with M.G.L. c. 30A and all applicable provisions of the Standard Adjudicatory Rules of Practice and Procedure 801 CMR 1.01 et seq.

(2) upon written request pursuant to 801 CMR 1.01 et seq., the applicant or licensee shall be afforded an opportunity for a hearing. Written requests for a hearing for any enforcement proceeding under 105 CMR 500.000 must be received by the Department within ten (10) days of the issuance of the Department's action.

(3) the failure to timely request a hearing constitutes a waiver of the right to a hearing.

(4) any settlement of any enforcement action commenced under 105 CMR 500.000 shall be final and shall not be subject to judicial review.

(5) a hearing based on an order for a summary suspension shall be conducted within 96 hours after the request for a hearing is received by the Department. If the 96 hour period expires on a weekend day or holiday, the hearing may be held on the next business day.



(6) a hearing based on a refusal to issue a license or a notice of intent to suspend, revoke or refuse to renew a license or to impose administrative penalties shall be commenced within a reasonable time period after the request for a hearing is received by the Department.

(7) failure to hold a hearing within the time periods specified herein shall not affect the validity of any order.

(8) the applicant or licensee shall be given an opportunity to be heard and to show why the order should be modified or withdrawn or why the proposed action should not be taken. Any oral testimony given at a hearing shall be recorded verbatim.

(9) in the case of summary suspension of a license, the hearing officer shall determine whether the Department proved by a preponderance of evidence that there existed, immediately prior to or at the time of the suspension, an imminent danger to the public health.

(10) in the case of a refusal to issue a license, or a notice of intent to suspend, revoke, refuse to renew, or to impose administrative penalties the hearing officer shall determine whether the Department proved by a preponderance of the evidence that the license should be denied, suspended, revoked or not renewed, or that administrative penalties should be imposed based on relevant facts as they existed at or prior to the time the Department initiated the action.

(11) the Notice of Violations/Order to Correct shall constitute prima facie evidence of the conditions listed therein.

(12) if the hearing officer finds any single ground for summary suspension, refusal to issue, suspension, revocation, or refusal to renew a license or the imposition of administrative penalties, the hearing officer shall render a recommended decision affirming the decision of the Department.

#### (I) Public Health Council and Judicial Review

(1) the recommended decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 500.017(H) shall be reviewed by the Commissioner and the Public Health Council. After review, their decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(2) any applicant, licensee, or other responsible person that fails to exercise his/her right to an adjudicatory proceeding or withdraws the request for a hearing, waives his/her right to administrative review by the Public Health Council. In such cases, the Commissioner shall issue the final agency decision. The failure to request an adjudicatory proceeding or the withdrawal of a request for an adjudicatory hearing shall be deemed a failure to exhaust administrative remedies.

#### (J) Embargoed Food

(1) Pursuant to M.G.L. c. 94, § 189A, the Commissioner or his agent or the local board of health, where applicable, may detain or embargo any food product which it finds or has probable cause to believe is adulterated or misbranded, provided that the Commissioner or his agent or the local board of health, where applicable, follow the procedures set forth in M.G.L. c. 94, §§ 186 through 189A.

(2) The Commissioner, or his agent, or the local board of health, where applicable, may place an embargo on any food which it knows or has probable cause to believe is adulterated or misbranded provided that:

(a) a written notice is issued to the licensee or the person in charge at the facility; and

(b) the notice specifies in detail the reason(s) for the embargo order.

(3) The Commissioner or his agent, or the local board of health, where applicable, shall tag, label, or otherwise identify any food subject to the embargo order. The tag or label shall state

that the food:

- (a) is believed to be adulterated or misbranded;
- (b) has been embargoed for ten days; and
- (c) cannot be removed, used, sold or disposed of without permission of the Commissioner or his agent, or the local board of health, where applicable.

(4) The Commissioner or his agent, or the local board of health, where applicable, shall permit storage of food under conditions specified in the embargo order, unless storage is not possible without risk to the public health, in which case immediate destruction shall be ordered and accomplished.

(5) If the food subject to embargo is found to be adulterated or misbranded, the Commissioner or his agent, or the local board of health, where applicable, shall take such steps as are necessary, pursuant to M.G.L. c. 94, §189A, to effect the condemnation and disposal or reconditioning of the food.

(6) If the food subject to the embargo order is not found to be adulterated or misbranded it shall be released.

#### (K) Criminal Penalties

Pursuant to the applicable provisions of M.G.L. c. 94 §§ 9E, 10, 73, 305A, 305C, or 305E, criminal penalties may be imposed.

#### (L) Nonexclusivity of Enforcement Procedures

None of the enforcement procedures contained in 105 CMR 500.000 is mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

#### 500.020 Severability

The provisions of 105 CMR 500.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be affected.

#### 500.030 Variance

(A) The Department may vary the application of any provision of 105 CMR 500.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice; provided, that the decision of the Department shall not conflict with the spirit of 105 CMR 500.000; and

(B) A copy of any such variance shall be available to the public.

#### REGULATORY AUTHORITY

105 CMR 500.000: M.G.L. c. 94, §§ 9F, 66, 67, 73A, 305A, 305C, and 305E.